

CFR 51.78: 60/122,076, filed March 1, 1999; 60/134,613, filed on May 18, 1999; 60/143,476, filed on July 12, 1999; 60/143,359, filed on July 12, 1999; and 60/170,997, filed on December 14, 1999. The application is also related to non-provisional application 09/473,510, now U.S. Patent No. 6,413,228, issued on July 2, 2002. The full disclosures of each application are incorporated herein by reference.

### **Remarks/Arguments**

#### **Status of the Claims**

The Office Action of December 2, 2004 has been received and considered. Claims 18-37 are pending. Claims 1-17 have previously been cancelled. Claims 18-37 have been rejected. An objection was set forth in the Office Action with respect to the specification. The specification has been amended. Reconsideration of the application is respectfully requested.

#### **Objection to the Specification**

The specification is objected to because the "Related Applications" section does not include the current patent number. Applicant was confused as to which issued patent the examiner was referring to in the Office Action mailed 7/22/04. Applicant apologizes for the confusion. The specification has been amended to reflect now issued U.S. Patent No. 6,585,706. Withdrawal of the objection to the specification is requested.

#### **The Rejections Under 35 U.S.C. §102(b) Should be Withdrawn**

Claims 18-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Jeter *et al.* (USP No. 5,683,420). The examiner maintains that the structure recited by the prior art is identical to the claimed structure. Applicants traverse this rejection.

As described in Applicant's response mailed October 20, 2004, the present invention claims an apparatus comprising at least two ductal access probes each having a lumen and being

configured for introduction into a respective one of the ductal networks of the breast for the purpose of simultaneously delivering a substance to at least two of the ductal networks and collecting a ductal fluid sample from the at least two ductal networks using a plurality of said introduced ductal access probes. Jeter *et al.* does not disclose a device configured to extract or collect these enhancement fluids from a breast. In the Office Action mailed 7/22/2004, the examiner notes multiple access probes in Figure 3. However, the device in Figure 3 lacks structure for the removal of fluid infused into a breast. Thus, the device cannot anticipate any claim reciting such structure. The examiner also notes in the 7/22/04 Office Action that “[A]s regards the collection tube, note Jeter syringe 16.” Syringe 16 is only depicted in Figure 4 of Jeter *et al.* Figure 4 of Jeter *et al.* does not depict an apparatus comprising at least two ductal access probes. Therefore, no specific device described or contemplated in Jeter *et al.* contains all the limitations of the device of the present invention. The examiner is attempting to combine pieces from different devices depicted in Jeter *et al.* in order to anticipate the claims of the present invention. This is inappropriate. Anticipation under 102(b) requires that every element of the claimed invention must be literally present, arranged as in the claim (emphasis added) (see Perkin-Elmer Corp., 732 F. 2<sup>nd</sup> at 894, 221 USPQ at 673; Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771-72, 218 USPQ 781, 789 (Fed.Cir.1983)). Jeter *et al.* discloses entirely different devices, composed of parts distinct from those of the claimed invention and operating in a completely different manner to produce a completely different outcome. The examiner states that “...the structure recited by the prior art is identical to the claimed structure.” (emphasis added). This is clearly not true. There is no device shown or described in Jeter *et al.* that is identical to the device of the present invention.

The examiner states that “[i]f the prior art structure is capable of performing the intended use; then it meets the claims”. Applicants disagree that the prior art structure described in Jeter *et al.* is capable of simultaneously delivering and collecting a ductal fluid sample from the ductal networks. Thus, Jeter *et al.* does not anticipate the claims of the present invention, in particular, independent claims 18 and 28 and all claims depending therefrom.

The examiner has also not described how dependent claims 19 through 27 and claims 29-36 are anticipated by Jeter *et al.* Claims 21, 24, and 25 describe a plurality of receptacles or collection tubes, for receiving material collected from respective ductal networks. The examiner has not pointed out where in Jeter *et al.* there is any description of a device having more than one receptacle or collection tube. Thus claims 21, 24, and 25 are not anticipated by Jeter *et al.*

Likewise, claim 22 describes a step of collecting fluid from each accessed ductal network, wherein the fluid is collected separately so that fluid from one of the ductal networks is free of fluid from another of the ductal networks. The prior art structure in Jeter *et al.* is clearly not capable of performing this intended use. Thus claim 22 is not anticipated by Jeter *et al.*

Claim 23 describes the closing of fluid flow valves in each of the lumens. There are no flow valves described anywhere in Jeter *et al.* Thus claim 23 is not anticipated by Jeter *et al.*

Claim 26 describes a manifold having at least two outlets wherein at least one outlet is connected to at least one ductal access probe and at least one the outlets is free of a connection to one of the ductal access probes and at least one unconnected outlet is closed to fluid flow. Jeter *et al.* does not describe a device with a manifold with at least one the outlets free of a connection to one of the ductal access probes and at least one unconnected outlet is closed to fluid flow. Thus claim 26 is not anticipated by Jeter *et al.*

Claim 27 describes ductal access probes which are removably connectable to a manifold and wherein at least one of the outlets is configured upon removal of a respective one of the ductal access probes therefrom, for closure to fluid flow. Jeter *et al.* does not describe a device with ductal access probes which are removably connected to a manifold. Thus claim 27 is not anticipated by Jeter *et al.*

Accordingly, for the reasons stated above, claims 18 and 28 and all claims depending therefrom (19-27 and 29-36) are allowable. Withdrawal of the rejection is requested.

#### Conclusion

In light of the arguments presented above, Applicants respectfully submit that the claims are in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.025011.

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